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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,994	12/03/2003	Kedar R. Belhe	47563.0015	4512

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EXAMINER	
WOO, JULIAN W	

ART UNIT	PAPER NUMBER
3773	

MAIL DATE	DELIVERY MODE
04/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/726,994	BELHE ET AL.	
	Examiner	Art Unit	
	Julian W. Woo	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 21-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 21-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 12, 2008 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3-7, 11-18, and 21-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Modesitt et al. (6,136,010). Modesitt et al. disclose, at least in figures 4-5, 11A-11E, and 13 and in col. 10, line 18 to col. 11, line 29; a vascular closure device and a method with the device for closing a vascular opening; where the device includes first and second needles (38, 38'), a suture (34), a snare (40 and/or 42—see fig. 4) configured to grasp suture), the snare being configured to move with the second needle from a retracted position to an extended position; a pre-tied knot (80), a handle (20), and an anchor (24) configured to extend through an opening in a blood vessel, the

anchor being configured to move between a contracted configuration where the anchor is sized to fit through the opening in the blood vessel and an expanded configuration where the anchor is too large to fit through the opening in the blood vessel; where the first and second needles extend outward and way from a sheath (12) at an angle of 3 deg. to 20 deg.; where a needle (38 or 38') is positioned at a distal end of the device, where a suture (34) is configured to move with the needle from a retracted position to an extended position, where a portion of the suture extends lengthwise from a tip of the needle toward a proximal end of the device and outside of the needle (see fig. 11A) where the method includes inserting a sheath or sleeve (12) into a vessel, inserting a snare (40 and/or 42) and a needle (38) on a first side of a vessel opening, inserting a suture (34) and another needle (38') on a second side of the opening, grasping the suture with the snare, pulling the suture across the vessel opening (see fig. 11d), directing the distal end of the suture through a pre-tied knot (80) at a proximal end of the suture, cinching the knot or tightening the suture, disengaging and withdrawing the sheath (12) from the vessel opening; where the device is secured in the blood vessel (via 24), where the sheath is anchored in the vessel with a pair of extendable feet (24a and 24b or 22 and 24), and where a safety wire (GW) can be inserted into the vessel opening and be used to facilitate reinsertion of the sheath.

4. Claims 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Evans et al. (5,728,114). Evans et al. disclose, at least in figures 7-12 and in col. 7, line 28 to col. 8, line 20; a vascular closure device including an anchor (22) configured to extend through an opening in a blood vessel, the anchor being configured to move between a

contracted configuration (see fig. 10), where the anchor is sized to fit through the opening in the blood vessel and expanded configuration (see fig. 11) where the anchor is too large to fit through the opening in the blood vessel, a snare (42) configured to be inserted through a wall of the blood vessel at a location that is adjacent to the opening in the blood vessel (within the blood vessel); a suture (24) configured to be inserted through the wall at another location adjacent the opening, the snare also being configured to grasp the suture in the blood vessel and retract the suture through the wall of the blood vessel, where the device is configured to close the opening in the blood vessel (see figs. 9-11), where the snare comprises a wire loop (42) having a memory that causes the loop to open in a repeatable orientation (i.e., the loop is flexible), where the snare and the suture each move between a retracted position and an extended position to allow the snare and the suture to be inserted through the wall of the blood vessel (from within the blood vessel), and where the device further comprises a handle set (26 and 28) to allow an operator to control movement of the snare and the suture.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Riza (5,562,688) in view of Goldrath (5,330,488), and further in view of Kammerer (5,562,684). Riza discloses the invention substantially as claimed. Riza discloses, at least in figure 5, a device including a needle movable between retracted and extended positions with respect to a tubular housing (11), a suture (81), and a snare (84) configured to move with the needle, where the snare comprises a wire loop (84) having a memory as claimed. However, Riza does not disclose another needle configured to be movable between retracted and extended positions with respect to the tubular housing (11) and a suture movable with another needle between retracted and extended positions, where the suture proximal end includes a pre-tied knot. Nevertheless, Riza discloses, in col. 8, lines 25-28, that elongated tools may be inserted into the tubular housing for manipulation of suture. Goldrath teaches, at least in figures 2 and 6, an elongated tool or needle (40) for manipulation of suture. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Goldrath, to apply a needle for carrying and manipulation of a suture in the Riza's device. Such a needle would allow the guidance of suture into relatively

inaccessible or closed surgical sites, where a suturing procedure can further be more performed with the use of a snare as disclosed by Riza (and as also taught by Goldrath). Moreover, Kammerer teaches, at least in figures 16-25 a suture (100) with a pre-tied knot (102) on its proximal end. It also would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Kammerer, to include a pre-tied knot with the suture of Riza's device. Such a knot would allow a quick and convenient means for tying and tightening a suture around tissues to be joined together.

7. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens (5,722,981) in view of Kammerer (5,562,684). Stevens discloses the invention substantially as claimed. Stevens discloses, at least in figures 7(a)-7(c); a vascular closure device, where the device includes first and second needles (112, 113) configured to move between retracted and extended positions, a suture (121) configured to move with the first needle, and a snare (119) configured to move with the second needle, the snare including a wire loop having a memory; where the wire loop opens adjacent to the first needle to grasp the suture. However, Stevens does not disclose a pre-tied knot disposed on a proximal end of the suture such that a distal end of the suture can be directed through the pre-tied knot. Kammerer teaches, at least in figures 16-25, a suture (100) with a pre-tied knot (102) on its proximal end. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Kammerer, to include a pre-tied knot with the suture of Stevens's

device. Such a knot would allow a quick and convenient means for tying and tightening a suture around tissues to be joined together.

8. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sierra et al. (5,496,332) in view of Kammerer (5,562,684). Sierra et al. disclose the invention substantially as claimed. Sierra et al. disclose, at least in figures 2-6, a method of closing a vascular opening utilizing a vascular closure device, where the method includes inserting a sheath (12)into a vessel through a vessel opening, inserting a snare (34) into the vessel on a first side of the vessel opening (i.e., the perimeter of the opening), the snare including a wire loop; inserting a suture (66 or 68) into the vessel on a second side of the vessel opening, extending the wire loop across the vessel opening to grasp the suture; and pulling the suture across the vessel opening the through the vessel on the first side of the vessel opening. However, Sierra et al. do not disclose directing the distal end of the suture through a pre-tied knot formed on a proximal end of the suture to create a knot to approximate tissue. Kammerer teaches, at least in figures 16-25, a suture (100) with a pre-tied knot (102) on its proximal end. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Kammerer, to include a pre-tied knot with the suture of Sierra et al. and to direct the distal end of the suture through the pre-tied knot. Such a knot and method step would allow a quick and convenient means for tying and tightening a suture around tissues to be joined together.

Response to Amendment

9. With respect to arguments regarding the rejection of claims under 35 U.S.C. 102 and based on the reference of Modesitt et al.: Modesitt et al. indeed disclose the elements recited in the claims. Specifically, element 40 (not 74) qualifies as the snare recited in claims 1, 7, 13, and 24. With respect to claims 21 and 24, Modesitt et al. also disclose a suture (34) movable with a needle from a retracted position to an extended position, where the suture extends from a tip of the needle toward a proximal end of the vascular closure device and outside of the needle. A portion of the suture shown in phantom in the figures also includes a portion of suture outside of the needle. The suture is also inserted through the wall of the blood vessel (from within the blood vessel) at a location adjacent to the opening or on a second side.

With respect to arguments regarding the rejection based on the reference of Evans et al.: Evans et al. indeed discloses an anchor “configured to move between a contracted configuration where the anchor is sized to fit through the opening in the blood vessel and an expanded configuration where the anchor is too large to fit through the opening in the blood vessel." That is, the recitation that an element is “configured to” and "sized to” perform a function is not a positive limitation but only requires the ability to so perform. In other words, the anchor of Evans et al. is capable of performing the function as claimed, and the shape and size of the anchor can vary according to the shape and size of a vascular opening. Evans et al. indeed disclose the apparatus as claimed, and Evans et al. happen to show one use of the apparatus in the figures (i.e., a method that is different from the Applicant's method).

With respect to arguments regarding the rejection of claims under 35 U.S.C. 103 and based on the references of Riza, Goldrath, and Kammerer: The Examiner disagrees with the Applicant's contention that a pre-tied knot, if used with the trocar gripper (10) of Riva, would "serve to suture the trocar gripper 10 to the opening in the patient." On the contrary, the pre-tied knot, as taught by Kammerer, is applied with a surgical port having an opening, where the pre-tied knot is separate from (i.e., not tied to) the port, and where the port is analogous in structure and function to the trocar gripper of Riza. The pre-tied knot in Kammerer does not serve to suture the port to an opening in a patient, and in analogy, a pre-tied knot applied in the device of Riza would not serve to suture the trocar gripper to the opening in the patient.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773

May 2, 2008